

III. Remarks

All of the pending claims 1-24 stand rejected under 35 U.S.C. Section 112, first paragraph, as being non-enabled "for the broad group of photochromic dyes or the structures claimed in claims 4-6." Official Action, p. 2. More particularly, the examiner takes the position that the specification teaches "only how to make dinitrobenzyl pyridine and gives no guidance as to how the other myriad of claimed compounds may be made."

Id. Applicant respectfully disagrees.

Under Section 112, first paragraph, the specification of a patent is enabling if it teaches those of ordinary skill in the art how to make and use the claimed invention without undue experimentation. *See Genentech, Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997). Determining whether or not a claimed invention is enabled is resolved under the analytic framework set forth in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), according to which consideration must be given, *inter alia*, to the state of the prior art, the level of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation. *Id.* The burden is initially the examiner's to make the determination of enablement or non-enablement giving consideration to "all the evidence related to each of [the Wands] factors," and to "establish a reasonable basis to question the enablement provided for the claimed invention." M.P.E.P. §§ 2164.01(a), 2164.04. Since the examiner's burden is to consider all of the Wands factors, and further in view of the fact that an invention may be disclosed by working as well as "prophetic" examples, it follows that "[t]he presence of only one working example should never be the **sole** reason

for rejecting claims as being broader than the enabling disclosure...." M.P.E.P. § 2164.02. (Emphasis added.)

In spite of the foregoing obligation, it is in fact the case that the examiner in this instance has rejected all of the pending claims articulating no other reason than that the specification describes "only dinitrobenzyl pyridine." Official Action, p. 2. Such a rejection, failing as it does to establish a "reasonable basis" to question Applicant's presumptively accurate disclosure, *see In re Marzocchi*, 169 USPQ 367 (CCPA 1971), is legally improper and so fails to shift to Applicant the burden of rebuttal.

Notwithstanding the examiner's failure to establish a *prima facie* case, Applicant submits that the claimed invention is enabled by virtue of the numerous examples, working and prophetic, provided in the specification.

In relation to a claimed genus, "representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art would expect the claimed genus could be used in that manner without undue experimentation." M.P.E.P. § 2164.02. Here, Applicant discloses not only three "production" examples of various time-temperature integrators comprising dinitrobenzyl pyridine compounds in varying matrices, but further describes as prophetic examples myriad indicator compounds based upon the skeletal structures of Figs. 1 and 2, as well as particular exemplary prophetic compounds in Fig. 3. These teachings are coupled with further statements, applicable to the claimed genus as a whole, respecting matrices for indicators, the nature of the photochromic indicator reactions, variation of discoloration times, etc.

In the face of the foregoing, the examiner's bare contention that the prophetic examples associated with Figs. 1 and 2 could be made only with undue experimentation is without merit. Indeed, Applicant clearly defines numerous substituents for each skeletal structure, while, in contrast, the examiner offers no evidence to suggest that one of ordinary skill in the art would be engaging in anything other than routine experimentation in compounding such indicators.

Turning then to the rejections of the claims in view of the prior art, claims 1-3, 7, 9, 11, 16-19, and 23 stand rejected under 35 U.S.C. Section 102(b) as identically disclosed in Kanakkanatt, WO 96/06643. Applicant respectfully disagrees.

Kanakkanatt discloses multichromic polymers having utility in packaging materials, these polymers comprising photochromic, chemiochromic, thermochromic and piezochromic dyes. More particularly, Kanakkanatt teaches that the chemochromic dyes "function with packaged articles to indicate whether a gas or a volatile liquid was present inside the packaged article," p. 3, lines 23-25, that the **"photochromic dyes...indicate whether a packaged food or medical use product has been partially or fully sterilized by an irradiation process,"** *id.* at lines 11-14 (*emphasis added*), that the "piezochromic dyes...indicate whether the specific polymeric material was in compressive or tensile stress," p. 4, lines 18-20, and that the thermochromic dyes "indicate whether a polymer is currently or has in the past been exposed to a particular temperature." *Id.* at lines 7-8. In other words, the photochromic dyes of Kanakkanatt are taught to identify the one-time occurrence of a specific stimuli; namely, irradiation treatment of the packaged product.

Such disclosure is decidedly **not** anticipatory of a packaging substrate having a time-temperature integrator including at least one reversible indicator with photochromic properties, the at least one reversible indicator integrator characterized by a time and temperature dependent discoloration following photo-induced coloration thereof, all as instantly claimed.

Neither, for the same reasons, is the teaching of Kanakkanatt anticipatory of the inventive process of this application, recited in claims 19-24, which process comprises "providing a substrate for packaging of or for attachment to a product which is sensitive to aging and temperature, having a time-temperature integrator arranged in the region of the substrate, wherein the time-temperature integrator contains a matrix and at least one reversible indicator embedded therein, the at least one reversible indicator having photochromic properties on the basis of transfer reactions, and wherein further the at least one reversible indicator is characterized by a time temperature dependent discoloration following photo-induced coloration thereof; effecting photo-induced coloration of the reversible indicator; and determining the degree of time-related and temperature-related discoloration and the quality of the product taking into account the degree of discoloration."

The base claims being clearly patentable over the Kanakkanatt reference, Applicant respectfully submits that the rejection of the remaining claims 2-3, 7, 9, 11, 16-18, and 23 as being anticipated by Kanakkanatt is rendered moot. This fact notwithstanding, Applicant notes that the art of record, taken alone or in any permissible combination, fails to either anticipate or render obvious the invention of these claims. Should the examiner maintain

the rejections to the claims, Applicant reserves the right to place the claims in allowable form, argue the patentability thereof, and/or appeal such rejection.

The examiner further rejects claims 4-6 and 8 under 35 U.S.C. Section 103(a) as being unpatentably obvious over Kanakkanatt, as applied above, in view of the publication of Corval et al. In particular, the examiner asserts that Kanakkanatt teaches the invention of claims 1-3 and 7, but fails to disclose photochromic dyes having the formula of claims 4 and 5. This argued deficiency, according to the examiner, is supplied by Corval et al., who the examiner contends teach 2-(2, 4-dinitrobenzyl) pyridine and 2-(2, 4-dinitrobenzyl)- 1, 10-phenanthroline to be photochromic compounds which "undergo a photochromic process from a photon transfer reaction." Official Action, p. 6. In view of the foregoing, the examiner alleges that "[i]t would have been obvious...to issue [sic] these compounds in the packaging materials of Kanakkanatt '643 due to their ability to change visually I [sic] response to radiation light." *Id.* Applicant strenuously disagrees.

A *prima facie* case of obviousness requires, *inter alia*, that "all the claim limitations must be taught or suggested by the prior art." M.P.E.P. § 2143.03 (*citing In re Royka*, 180 USPQ 580 (CCPA 1974)).

In the present case, even assuming, *arguendo*, the propriety of both the asserted teachings of Kanakkanatt and Corval et al. and the argued motivation to combine these teachings, it remains the case that these references fail to comprehend Applicant's invention **at least** because Kanakkanatt and Corval et al. do not teach a packaging substrate having a time-temperature integrator comprising at least one reversible indicator with photochromic properties, the at least one reversible indicator characterized by a time and temperature

dependent discoloration following photo-induced coloration thereof. On this basis, Applicant respectfully submits that the rejection of claims 4-6 and 8 is unsustainable. Nevertheless, should the examiner maintain his rejection as to these claims, Applicant reserves the right to place the claims in allowable form, argue the patentability thereof, and/or appeal such rejection.

Finally, the examiner rejects claims 10, 12-15, 20-22 and 24, also under Section 103(a), as being unpatentably obvious over Kanakkanatt, as applied above, in view of U.S. Pat. No. 3,999,946, issued to Patel et al. More particularly, the examiner contends that Kanakkanatt, as applied above, teaches the instant invention but for the additional use of a non-reversible indicator. This deficiency is supposedly supplied by Patel et al., the examiner taking the position that that reference discloses the use of indicator dyes whose color change is irreversible. Relative to claims 13, 14 and 22, the examiner further contends that Patel et al. teach using a filter material. Relative to claims 15, 20 and 24, the examiner asserts that Patel et al. teach the use of a reference chart to compare the resulting color.

Even accepting, for the sake of argument, the examiner's characterization of the Patel et al. and Kanakkanatt references and the alleged motivation to combine those references, the examiner fails to establish a *prima facie* case of obviousness **at least** because Kanakkanatt and Patel et al. do not teach a packaging substrate having a time-temperature integrator comprising at least one reversible indicator with photochromic properties, the at least one reversible indicator characterized by a time and temperature dependent discoloration following photo-induced coloration thereof. Indeed, Patel et al. teaches compositions containing conjugated acetylene groups which exhibit irreversible color

changes (tending toward increasing intensity) in response to time and temperature. The examiner additionally falls short of even making a *prima facie* case of obviousness as to claims 13-15, 20-22 and 24 for want of *any* argued motivation to combine references.

In view of the foregoing, Applicant respectfully submits that the rejection of claims 10, 12-15, 20-22 and 24 is unsustainable. Nevertheless, should the examiner maintain his rejection as to these claims, Applicant reserves the right to place the claims in allowable form, argue the patentability thereof, and/or appeal such rejection.

IV. Conclusion

In view of the foregoing, Applicant submits that the claims are in condition for immediate allowance. Of course, the examiner is invited to contact Applicant's undersigned counsel at (734) 662-0270 if she should have any questions respecting this paper, or if a telephonic interview might otherwise expedite the prosecution of this case.

Respectfully submitted,

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Marked-Up Version of Claim 1 Showing Proposed Changes Thereto

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1. (Amended) Substrate for packaging of or for attachment to products which are sensitive to aging and temperature, having a time-temperature integrator arranged in the region of the substrate, [characterized in that] wherein the time-temperature integrator contains a matrix and at least one reversible indicator embedded therein, which has photochromic properties on the basis of transfer reactions, and wherein further the reversible indicator is characterized by a time and temperature dependent discoloration following photo-induced coloration thereof.



Marked-Up Version of Claim 2 Showing Proposed Changes Thereto

2. (Amended) Substrate according to claim 1, [characterized in that] wherein the substrate is a packaging material.

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Marked-Up Version of Claim 3 Showing Proposed Changes Thereto

3. (Amended) Substrate according to claim 1, [characterized in that] wherein the transfer reactions are based on the transfer of charged or uncharged hydrogen atoms or hydrogen isotopes.

Marked-Up Version of Claim 4 Showing Proposed Changes Thereto

4. (Amended) Substrate according to claim 1, [characterized in that] wherein the reversible indicator has a skeletal structure according to the general formula I;

(Formula page 2 of claims)

wherein A_1 - A_5 = carbon atom and/or heteroatom [,such as for example N, S, O]

R_1 - R_4 = hydrogen atom and/or isotope thereof, and/or Cl, F, Br ,or a substituent [,such as for example] selected from the group consisting of alkyl groups, [in particular] methyl or aryl groups, [in particular] and phenyl groups

R_5 = [H, D, or T] hydrogen atom or isotope thereof, or a substituent [,such as for example] selected from the group consisting of Cl, F, Br [or an alkyl group, in particular methyl group or an aryl group, in particular phenyl or pyridine, and] ,
an alkyl group, a methyl group, an aryl group, phenyl group, and pyridine

R_6 = [H, D, T] hydrogen atom or isotope thereof

B_1 - B_7 = carbon atom and/or heteroatom [,such as for example N, S, O]

R_1-R_{10} = hydrogen atom and/or an isotope thereof, and/or one or more Cl, F, Br, amino groups, [or] nitro groups, or one or more substituents [, such as for example] selected from the group consisting of alkyl groups, [in particular] methyl or aryl groups, [in particular] and phenyl groups, [and]

R_{11} = nitro group or a cyano group or a carboxylic acid group or a variant [, such as for example] selected from the group consisting of an ester, amide, ketone or aldehyde group.

Marked-Up Version of Claim 5 Showing Proposed Changes Thereto

5. (Amended) Substrate according to claim 1, [characterized in that] wherein the reversible indicator has a skeletal structure according to the general formula II:

(Formula page 3 of claims)

wherein A_1-A_{12} = carbon atom and/or a heteroatom [,such as for example N, S, O]

R_1-R_7 = hydrogen atom and/or isotope thereof, and/or Cl, F, B, or [other] substituents [, such as for example] selected form the group consisting of alkyl groups, [in particular] methyl or aryl groups, [in particular] and phenyl groups

R_8 = [H, D, T] hydrogen atom or isotope thereof, or a substituent [, such as for example] selected from the group consisting of Cl, F, Br [or], an alkyl group, [in particular] phenyl group, [or] and pyridine

R_9 = [H, D, T] hydrogen atom or isotope thereof

B_1-B_7 = carbon atom and/or heteroatom [,such as for example N, S, O]

$R_{10}-R_{13}$ = hydrogen atom and/or isotope thereof, and/or one or more Cl, F, Br, amino groups, [or] nitro groups, or one or more substituents [, such as for example] selected from the group consisting of alkyl groups, [in particular] methyl or aryl groups, [in particular] and phenyl groups.

Marked-Up Version of Claim 6 Showing Proposed Changes Thereto

6. (Amended) Substrate according to claim 4, [characterized in that] wherein in the general formula I [and II], $R_4 = NO_2$ and 2-4 NO_2 groups are present.

Marked-Up Version of Claim 7 Showing Proposed Changes Thereto

7. (Amended) Substrate according to claim 1, [characterized in that] wherein the transfer reactions are based on large, charged or uncharged groups.

Marked-Up Version of Claim 8 Showing Proposed Changes Thereto

8. (Amended) Substrate according to claim 1, [characterized in that] wherein the transfer reactions are based on a charged or uncharged halogen atom.

Marked-Up Version of Claim 9 Showing Proposed Changes Thereto

9. (Amended) Substrate according to claim 1, [characterized in that] wherein the reversible indicator has more than one characteristic time domain.

Marked-Up Version of Claim 10 Showing Proposed Changes Thereto

10. (Amended) Substrate according to claim 1, [characterized in that] wherein at least two reversible indicators having different characteristic time domains are embedded in the matrix.

Marked-Up Version of Claim 12 Showing Proposed Changes Thereto

12. (Amended) Substrate according to claim 1, [characterized in that] wherein at least one irreversible indicator having photochromic properties is arranged in the region of the reversible indicator.

Marked-Up Version of Claim 13 Showing Proposed Changes Thereto

13. (Amended) Substrate according to claim 1, [characterized in that] wherein the time-temperature integrator has a filter which is impermeable to light [,] which effects photo-induced coloration of the reversible indicator.

Marked-Up Version of Claim 14 Showing Proposed Changes Thereto

14. (Amended) Substrate according to claim 13, [characterized in that] wherein the filter is impermeable to light in the wavelength range of [a wavelength preferably] below approximately 430 nm.

Marked-Up Version of Claim 15 Showing Proposed Changes Thereto

15. (Amended) Substrate according to claim 1, [characterized in that] wherein the substrate includes a reference scale arranged in the region of the time-temperature integrator.

Marked-Up Version of Claim 16 Showing Proposed Changes Thereto

16. (Amended) Substrate according to claim 1, [characterized in that] wherein the matrix is a polymer film.

Marked-Up Version of Claim 17 Showing Proposed Changes Thereto

17. (Amended) Substrate according to claim 1, [characterized in that] wherein the substrate is a polymer film.

Marked-Up Version of Claim 18 Showing Proposed Changes Thereto

18. (Amended) Substrate according to claim 1, [characterized in that] wherein a substrate region forms the matrix for the reversible indicator.

Marked-Up Version of Claim 19 Showing Proposed Changes Thereto

19. (Amended) Process for determination of quality of products which are sensitive to aging and temperature [and are provided with a substrate according to one of claims 1, containing the steps] comprising the steps of :

a) providing a substrate for packaging of or for attachment to a product which is sensitive to aging and temperature, having a time-temperature integrator arranged in the region of the substrate, wherein the time-temperature integrator contains a matrix and at least one reversible indicator embedded therein, the at least one reversible indicator having photochromic properties on the basis of transfer reactions, and wherein further the reversible indicator is characterized by a time and temperature dependent discoloration following photo-induced coloration thereof;

[a)] b) effecting photo-induced coloration of the reversible indicator; and

[b)] c) [determination of] determining the degree of time-related and temperature-related discoloration and the quality of the product taking into account the degree of discoloration.

Marked-Up Version of Claim 20 Showing Proposed Changes Thereto

20. (Amended) Process according to claim 19, [characterized in that] wherein the determination of the quality of the product is effected by evaluating the degree of discoloration with the aid of a reference scale.

Marked-Up Version of Claim 21 Showing Proposed Changes Thereto

21. (Amended) Process according to claim 19, [characterized in that] further comprising the step of providing an irreversible indicator having photochromic properties, the irreversible indicator arranged in the region of the reversible indicator, and wherein further the irreversible indicator is applied after [optically]photo-induced coloration of the reversible indicator.

Marked-Up Version of Claim 22 Showing Proposed Changes Thereto

22. (Amended) Process according to claim 19, [characterized in that] further
comprising the step of providing the time-temperature integrator with a filter that is
impermeable to light which effects photo-induced coloration of the reversible indicator,
and wherein further the filter is applied after [optically] photo-induced coloration.

Marked-Up Version of Claim 23 Showing Proposed Changes Thereto

23. (Amended) Process according to claim 19, [characterized in that] wherein the [optically] photo-induced coloration of the reversible indicator is effected by UV or near UV light.

Marked-Up Version of Claim 24 Showing Proposed Changes Thereto

24. (Amended) Process according to claim 19, [characterized in that] wherein the [optical] photo activation of the time-temperature integrator is effected by irradiation of the side of the time-temperature integrator opposite the filter.